IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OHIO

JOIEL D. BAUSCHATZ, ADMINISTRATOR OF THE ESTATE OF JAMES M. BAUSCHATZ, DECEASED

AND

JOIEL D. BAUSCHATZ, SURVIVING SPOUSE OF JAMES D. BAUSCHATZ

Plaintiffs,

v.

CARACO PHARMACEUTICALS LABORATORIES, LTD.

Defendant.

Case No. _____

COMPLAINT

PLAINTIFF, JOIEL D. BAUSCHATZ, as surviving spouse and administrator of the estate of James M. Bauschatz, deceased, through her undersigned attorney, hereby commences this individual action against CARACO PHARMACEUTICALS LABORATORIES, LTD. (hereinafter collectively "Defendant" unless otherwise stated) for compensatory and punitive relief.

I. JURISDICTION & VENUE

1. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 because the parties are citizens of different states and the matter in controversy exceeds the jurisdictional amount exclusive of interests and costs.

2. Venue is proper under 28 U.S.C. § 1391 because Defendant transacted substantial business in this District and in Ohio.

II. PARTIES

3. Plaintiff is the administrator of the estate and the surviving spouse of James M. Bauschatz, deceased.

4. At all times relevant to this Complaint, Plaintiff was a citizen of the United States and a resident of Lake County, Ohio.

5. Defendant, Caraco Pharmaceuticals Laboratories, Ltd. is a Michigan corporation organized, existing and conducting business in the State of Michigan with its principal place of business at 1150 Elijah McCoy Drive, Detroit, Ml 48202. At all times relevant to this Complaint, Caraco Pharmaceuticals Laboratories, Ltd. was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digoxin, including to the decedent, James M. Bauschatz. At all times relevant hereto, the defendant Caraco Pharmaceuticals Laboratories, Ltd., regularly transacted, solicited and conducted business in North East Ohio including the marketing, promoting, testing, selling and/or distribution for sale of Digoxin.

Ill. INTRODUCTION

6. Caraco Pharmaceuticals Laboratories, Ltd. designed, researched, tested, and manufactured Digoxin.

7. Digoxin is widely used in the treatment of various heart conditions including atrial fibrillation, atrial flutter and heart failure. The United States Food and Drug Administration approved the medication to be manufactured, distributed and sold with approved levels of active ingredient.

8. Digoxin was a mass-marketed product and widely sold throughout the United States, including Ohio and more specifically, North East Ohio.

9. Defendant was negligent in the design, testing, manufacturing, advertising, marketing, promotion, labeling, warnings given and sale of Digoxin because the medication was provided for use by the public with twice the approved level of active ingredient.

10. Digoxin has a narrow therapeutic index, and thus, has a limited margin between effectiveness and toxicity.

11. Ingestion of excess levels of the active ingredient in Digoxin beyond the level approved by the FDA can cause death and other health problems.

12. Upon information and belief, defendant received multiple complaints about significant adverse side effects including illnesses and injuries from Digoxin since 2006.

13. Defendant has a history of releasing drug products for public consumption that have been adulterated or misbranded.

14. Defendant has a history of failing to establish the identity, strength, quality and purity of drug products they release for public consumption.

15. Defendant has a history of failing to adequately investigate and document test results on their drug products.

16. Defendant failed to adequately warn users of the defective drug of its unreasonably dangerous characteristics resulting from the excess level of the active ingredient contained in the drug.

17.Decedent JAMES M. BAUSCHATZ, was prescribed Digoxin by his physician.

18. JAMES M. BAUSCHATZ suffered serious bodily injury resulting in his death, emotional distress, pain, loss of enjoyment of life and mental anquish as a direct and proximate result of his use of Digoxin.

19. Defendant's conduct in the design, testing, manufacturing, advertising, marketing, promotion,

labeling, warnings given and sale of Digoxin for use by the public with twice the approved level of active ingredient was a proximate cause of the injuries and death of James M. BAuschatz.

20. Defendant knew or, in the exercise of reasonable care, should have known that their drug was defective and that individual, including the decedent, would reasonably be expected to use their drug and would suffer injury as a result of normal use of the drug.

21. Defendant owed a duty to the decedent James M. Bauschatz, to design, manufacture, test, advertise, promote, sell and distribute Digoxin as approved by the FDA and without hidden and concealed defects.

22. Defendant breached said duty to JAMES M. BAUSCHATZ and this breach was a proximate caused his injuries, damages and death.

23. Numerous other consumers have been similarly injured by Defendants' wrongful conduct.

COUNT I

STRICT LIABILITY IN TORT

24. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

25. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed Digoxin which was used and ingested by Decedent JAMES M. BAUSCHATZ.

26. Digoxin was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said drug without substantial change in the condition in which it was produced, manufactured, tested, sold, distributed and marketed by Defendant.

27. At all times relevant to this Complaint, Digoxin was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users, specifically including Decedent JAMES M. BAUSCHATZ, because it contained excess levels of active ingredient.

28. Digoxin was so defective in design, formulation, manufacture and testing that when it left the hands of Defendant, the foreseeable risks exceeded the benefits associated with the design, formulation and manufacture of Digoxin.

29. Defendant knew, or should have known, at all times relevant herein, that Digoxin was in a defective condition and was inherently dangerous and unsafe because it contained excess levels of active ingredient.

30. Decedent JAMES M BAUSCHATZ, used Digoxin for the purpose and manner normally intended for the drug.

31. Decedent JAMES M. BAUSCHATZ, acting as a reasonably prudent person, could not have discovered that Digoxin was defective, nor could he have perceived its danger.

32. Defendant had a duty to create a product that was safe for its normal, intended use.

33. Upon information and belief, sales, prescription, use and ingestion of the defective durg continued after Defendant knew, or should have known that their product contained excess levels of active ingredient, and therefore, presented risk of serious side effects including, but not limited to, nausea, vomiting, dizziness, low blood pressure, cardiac instability, bradycardia, toxicity and death, as well as other severe and permanent health consequences. Therefore, Defendant is strictly liable in tort for the bodily injuries, damages and death of Decedent JAMES M. BAUSCHATZ.

34. The Digoxin designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendant contained excess levels of active ingredient, and was therefore, an unreasonably dangerous product, not reasonably safe for sale to and use by the consumer, and did not meet reasonable consumer expectations because of design and manufacturing defects, use defects including inadequate warnings, and defects attributable to inadequate testing and monitoring. Defendant is therefore, strictly liable for the injuries, damages and death of Decedent JAMES M. BAUSCHATZ.

35. The Digoxin designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendant contained excess levels of active ingredient, and therefore, was defective due to inadequate post-marketing surveillance and/or warnings. Defendants are, therefore strictly liable for the injuries, damages and death of the Decedent JAMES M. BAUSCHATZ.

36. The Digoxin designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was unreasonably dangerous, because (a.) The manufacturing processes for the drug did not satisfy the Food and Drug Administration's manufacturing standards;

(b.) The failure of the Defendant's manufacturing process for the drug to satisfy the Food and Drug Administrations' applicable manufacturing standards resulted in unreasonably dangerous manufacturing defects, and

(c.) The Defendant failed to warn of the unreasonable risks created by these manufacturing defects.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of $25,000.00 sufficient to fully compensate for all losses proximately resulting from the actions or inactions of said Defendant and for interest at the maximum lawful rate permitted by law, and for the costs of this action.

COUNT II

NEGLIGENCE

Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

37. Defendant failed to exercise reasonable care and was negligent through the following acts and omissions:

(a.) Manufacturing, designing, promoting, formulating, creating, marketing, packaging, distributing and selling Digoxin in violation of FDA drug approved requirements because the drug was released for public consumption with excess levels of active ingredient beyond that approved by the FDA;

(b.) Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling Digoxin in violation of FDA drug approved requirements because the drug was released for public consumption with excess levels of active ingredient beyond that approved by the FDA; without properly testing it to ensure it did not have excess levels of active ingredient;

(c.) Manufacturing, designing, producing, promoting, formulating, creating, marketing, packaging, distributing and selling Digoxin in a manner that was dangerous to intended users.

(d.) Failing to adequately warn, timely recall or otherwise notify health care providers and users at the earliest date that it became known that Digoxin was dangerous and defective because it contained excess levels of active ingredients;

(e.) Negligently advertising and recommending the use of Digoxin without ensuring the safety of the

drug for its intended use;

(f.) Failing to reliably establish the identity, strength, quality and purity of the Digoxin that Defendant released into the market; and

(g.) Failing to conduct adequate post-marketing surveillance to ensure the safety of Digoxin.

38. Defendant under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digoxin.

39. Defendant knew or should have known that consumers such as the Decedent would suffer injury, including death, as a result of Defendant's failure to exercise ordinary care as outlined above.

40. The Defendants were negligent in the manufacturing of Digoxin because:

(a.) Their manufacturing process for the drug did not satisfy the Food and Drug Administration's manufacturing standards;

(b.) The failure to satisfy the FDA manufacturing standards resulted in unreasonably dangerous manufacturing defects, and

(c.) The Defendants failed to warn of the unreasonable risks created by these manufacturing defects.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of $25,000.00 sufficient to fully compensate for all losses proximately resulting from the negligence of said Defendant and for interest at the maximum level rate permitted by law, and for the costs of this action.

COUNT III

BREACH OF IMPLIED WARRANTY

41. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

42. Ohio law imposes a duty on the seller of a product to warrant that a product is reasonably fit for its intended purpose.

43. Defendant, as a seller of Digoxin, warranted that the drug was safe for its intended purpose.

44. Decedent, JAMES M. BAUSCHATZ, reasonably relied on the belief that Digoxin was reasonably safe and fit for its intended purpose.

45. Defendant breached their implied warranty by releasing for public consumption, a product which contained twice the amount of the approved and expected active ingredient and that was not safe and fit for its intended purpose.

46. Defendant's breach of this implied warranty was a proximate cause of the Decedent's bodily injury, damages and death.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of

$25,000.00 sufficient to fully compensate for all losses proximately resulting from the breach of said Defendant and for interest at the maximum lawful rate permitted by law, and for the costs of this action.

COUNT IV

BREACH OF EXPRESS WARRANTY

47. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

48. Defendant expressly warranted that Digoxin would be reasonably safe and fit for its intended purpose.

49. Decedent reasonably relied on the express warranty of Defendant that Digoxin was reasonably safe and fit for its intended use.

50. Digoxin does not conform to the express warranties by Defendant because the drug, as produced for public consumption, is defective and presents a high risk for injury and death to its intended users.

51. Defendant breached its express warranty regarding the safety and fitness of Digoxin.

52. Defendant's breach of its express warranty was a proximate cause of Decedent's bodily injury, damages and death.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of $25,000.00 sufficient to fully compensate for all losses proximately resulting from the breach of said

Defendant and for interest at the maximum lawful rate permitted by law, and for the costs of this action.

COUNT V

WRONGFUL DEATH

53. Plaintiff, Administrator of the estate of James M. Bauschatz, brings this claim for wrongful death, on behalf of the heirs of James M. Bauschatz.

54. As a result of the acts and omissions of the Defendant that ultimately caused the death of James m. Bauschatz, his family and heirs have been, and will continue to be, deprived of his companionship, society, comfort, protection and service, and have suffered and will continue to suffer, grief, sorrow, mental anguish, emotional distress and pain and suffering, and are therefore entitled to damages for wrongful death.

55. As a further, direct and proximate result of the acts and omissions of Defendant, Plaintiff Joiel Bauschatz, individually and as Personal Representative, has been damaged in that she has and will continue to suffer grief, loss of companionship, loss of care, comfort, society, protection, support, love and services of Decedent.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of $25,000.00 sufficient to fully compensate for all losses proximately resulting from the breach of said Defendant and for interest at the maximum lawful rate permitted by law, and for the costs of this action, general and special monetary damages in a sum to be ascertained according to proof at the time of trial, including but not limited to, medical and burial expenses, and mental pain and anguish suffered by the Decedent.

COUNT VI

PUNITIVE DAMAGE CLAIM

56. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

57. Defendant's pattern and practice of permitting adulterated drug products to be released for consumer use; concealing the existence of the defects and adulterations; failing to reliably establish the identity, strength, quality and purity of drug products that they manufacture and release onto the market; and failure to investigate and document out-of-specification test results, constitutes an irresponsible, wanton and reckless attitude toward the safety and health of the public, including Decedent. Such conduct was willful, deliberate, intentional, reckless and/or malicious and proximately caused Decedent's bodily injuries, damages and death.

58. Defendants concealment of the dangers presented to the consumer, including the Decedent even after it defendant that Digoxin had been released to the general public with twice the levels of active ingredient was willful, deliberate, intentional, reckless, and/or malicious and was a proximate cause of Decedent's bodily injury, damages and death.

59. Defendant's failure to timely and effectively notify the public, including Decedent, that Digoxin had been released to the general public with twice the levels of active ingredient was willful, deliberate, intentional, reckless, and/or malicious and was a proximate cause of Decedent's bodily injury and damages.

WHEREFORE, Plaintiff is entitled to pray for an award of damages in excess of $75,000.00 and for punitive damages as a result of the deliberate, willful, intentional, reckless and/or malicious conduct of Defendant outlined herein.

JURY DEMAND

Plaintiff hereby requests a trial by jury.

Respectfully submitted;

DAVID H. DAVIES
Attorney for Plaintiff
P.O. Box 1264
Willoughby, Ohio 44096
(440) 953-2000
Registration No.: 0016318